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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SMITH, CAROLYN L	
ART UNIT	PAPER NUMBER
	7

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/978,418	BEJANIN ET AL.	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-13* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

4)☐ Interview Summary (PTO-413) Paper No(s) _____

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other.

DETAILED ACTION

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to an isolated polynucleotide, classified in class 536, subclass 23.1. If this Group is elected, then the below summarized sequence election is also required.

II. Claim 2, drawn to a polypeptide, classified in class 530, subclass 350. If this Group is elected, then the below summarized sequence election is also required.

III. Claims 3-4, drawn to a method of making a polypeptide, classified in class 435, subclass 69.1. If this Group is elected, then the below summarized sequence election is also required.

IV. Claim 5, drawn to an antibody, classified in class 530, subclass 387.1. If this Group is elected, then the below summarized sequence election is also required.

V. Claim 6, drawn to a method of binding a polypeptide to an antibody, classified in class 435, subclass 7.1. If this Group is elected, then the below summarized sequence election is also required.

VI. Claims 7-9, drawn to a method of determining whether a GENSET gene is expressed within a mammal, classified in class 435, subclasses 6 and 7.1. If this Group is elected, then the below summarized sequence election is also required. Also, if this Group is elected, then the below summarized specie election is also required.

VII. Claim 10, drawn to a method of determining whether a mammal has an elevated or reduced level of GENSET gene expression, classified in class 435, subclass 69.1. If this Group is elected, then the below summarized sequence election is also required. Also, if this Group is elected, then the below summarized specie election is also required.

VIII. Claims 11-12, drawn to a method of identifying a candidate modulator of a GENSET polypeptide, classified in class 435, subclass 7.1. If this Group is elected, then the below summarized sequence election is also required.

IX. Claim 13, drawn to a method of producing a pharmaceutical composition, classified in class 514, subclass 2. If this Group is elected, then the below summarized sequence election is also required.

Sequence Election Requirement Applicable to All Groups:

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid/polypeptide sequences, the Applicants must further elect a single amino acid/polypeptide sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic acid sequence (See MPEP 803.04). It is noted that the multitude of sequence submissions of examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 nucleic acid sequences effectively impossible to reasonably implement.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction requirement and not a species election requirement.

Specie Election Requirement for Groups VI and VII:

This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A: a method involving polynucleotides

Specie B: a method involving polypeptides

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the claims in Groups VI and VII are generic to the above species. The reason for independence of polynucleotides versus polypeptides is because they are directed to different chemical types featuring different critical limitations. The separate chemical types of these species are often separately characterized and published in literature, thus adding to the search burden if all species were examined together. Also, processing that may connect two species does not prevent them from being considered distinct because enough processing can result in the

production of any composition from another composition as long as the processing is not limited in occurrences such as subtractions, additions, and enzymatic action. Thus, both species of Group VI and VII are independent and/or distinct invention types for restriction purposes.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups [I, III, VI (polynucleotide species), and VII (polynucleotide species of [II, V, VI (polypeptide species), VII (polypeptide species), VIII, and IX] are [V] independent inventions because they are directed to different chemical and entity types regardless of the critical limitations therein. For Groups I, III, VI (polynucleotide species), and VII (polynucleotide species); the critical feature is a polynucleotide. For Groups II, V, VI (polypeptide species), VII (polypeptide species), VIII, and IX; the critical feature is a polypeptide. For Group IV, the critical feature is an antibody. The completely disparate chemical and entity types of the invention Groups are often separately characterized and published in literature, thus adding to the search burden if all Groups were examined together. Also, processing that may connect two Groups does not preclude them from being considered distinct because enough processing can result in the production of any composition from another composition as long as the processing is not limited in occurrences such as subtractions, additions, and enzymatic action. Thus, the three Groupings: Groups [I, III, VI (polynucleotide species), and VII (polynucleotide species of [II, V, VI (polypeptide species), VII (polypeptide species), VIII, and IX], and [IV] are independent and or distinct invention types for restriction purposes.

Inventions in Groups [I, III, VI (polynucleotide species), and VII (polynucleotide species) are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 [e]). In the instant case the polynucleotide of Group I may be utilized in

distinct usages as needed in Group III for a method making a polypeptide, in a method of determining whether a GENSET gene is expressed within a mammal as in Group VI, in a method of determining whether a mammal has an elevated or reduced level of GENSET gene expression as in Group VII, or alternatively, in antisense therapy. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Inventions I, II, V, VI (polypeptide species), VII (polypeptide species), VIII, and IX are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II may be utilized in distinct usages as needed in Group V for a method of binding a polypeptide to an antibody, in a method of determining whether a GENSET gene is expressed within a mammal as in Group VI, in a method of determining whether a mammal has an elevated or reduced level of GENSET gene expression as in Group VII, in a method of identifying a candidate modulator of a GENSET polypeptide as in Group VIII, in a method of producing a pharmaceutical composition as in Group IX, or alternatively, in cell growth inhibition studies. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1989), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael W. Allen, can be reached on (703) 308-4028.

Any inquiry concerning this communication or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

John H. Marshall

January 7, 2003